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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,668	07/01/2003	Simon Jones	8702.0018-08000	3471

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,668

Applicant(s)

JONES ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-56 is/are pending in the application.
- 4a) Of the above claim(s) 48-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-39 and 56 is/are allowed.
- 6) ☒ Claim(s) 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and response received September 28, 2005 is acknowledged.

Claims 29, 40, and 44 have been amended.

Claim 56 has been added.

Claims 48-55 stand withdrawn as per the office action mailed January 11, 2005.

Claims 29-56 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 44-47 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement due to issues surrounding the deposit of biological materials has been withdrawn in light of deposit declaration of M. Andrea Ryan received September 28, 2005.

4. Claims 40-43 stand rejected and claim 44 as amended September 28, 2005 and its dependent claims 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing

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to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the office action mailed June 28, 2005.

Applicant's arguments filed September 28, 2005 have been fully considered but they are not persuasive. Applicant argues that only routine experimentation is required for a skilled artisan to determine which antibodies fall within the claimed genus of antibodies that hybridize to the complement of recited nucleic acid sequences. The examiner disagrees. As was indicated in the office action mailed June 28, 2005, the specification does not teach which mutations can or cannot be made to a polynucleotide that encodes a polypeptide such that the polypeptide maintains activity in a mixed micelle assay. Additionally, the polypeptides encoded by hybridizing nucleic acids as recited in claim 44 as amended September 28, 2005, are not required to have any functional activity. Although the claimed sequences are recited as hybridizing under relatively stringent conditions the polypeptides they encode encompass sequences that are less than 100% identical to the polypeptide sequences of SEQ ID NO:17, 19, 21, and 23. As such they contain mutations that can alter the activity of the enzyme. Determining which polypeptide sequences do or do not maintain the claimed activity is not predictable, and as such more than routine experimentation would be required to make such polypeptides as was indicated in the rejection of record. Since the polypeptides require more than routine experimentation, making antibodies that bind said polypeptides would also require more than routine experimentation, and it logically

follows that if the claimed subject matter cannot be made then it cannot be used.

Therefore, the rejection of record has been maintained.

5. The rejection of claims 44-47 U.S.C. 112, first paragraph, for lack of enablement of antibodies that bind to the polypeptides encoded by the complementary strand of recited SEQ ID numbers has been obviated by applicant's amendment to the claims received September 28, 2005 to clarify that the claimed material is actually the polypeptide encoded by a nucleic acid that hybridizes under stringent conditions to the full length complementary sequence of the recited SEQ ID numbers.

6. The rejection of claims 29-39 under 35 U.S.C. 112, first paragraph, for containing new matter concerning the limitation "epitope" has been withdrawn upon further consideration.

7. The rejection of claims 29-47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the limitation "purified" has been withdrawn upon further consideration and in light of applicant's persuasive arguments.

8. Claims 29-39 and 56 appear to be allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
December 2, 2005


Patrick J. Nolan, Ph.D.
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